

interval to surgery is a promising treatment because the pathological complete response (pCR) rate of over 20% was recorded. The body of evidence from studies that used conventionally fractionated radiochemotherapy showed that, with a longer interval to surgery, the pCR rate and downstaging increased, whereas the R0 resection rate, the sphincter preservation rate and the long-term oncological outcomes remained much the same. The desired effect of radiation, namely irreparable DNA damage which ceased clonogens division, occurs at the time of irradiation. A lengthening of the interval between radio(chemo)therapy and surgery does not produce additional DNA damage. With delayed surgery, there is a risk of tumour regrowth and the development of a cancer phenotype that produces distant metastases. Indeed evaluation of a labelling index showed the accelerated proliferation of cancer cells in some tumours one month after 5 x 5 Gy. PET/CT examinations demonstrated increased metabolic activity in some tumours between 6 and 12 weeks after chemoradiation. Thus, the long interval potentially jeopardizes oncological outcomes in up-front resectable cancers. This effect, however, was not shown in the randomized studies or in the meta-analysis.

OC-0610

Quality of life in patients undergoing radiotherapy and sphincter sparing surgery or rectal amputation

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Purpose/Objective: In patients with rectal cancer (chemo)radiotherapy is usually followed by low anterior resection (LAR) or abdominoperineal resection (APR) with permanent colostomy. Type of surgery depends on tumor localization, patient's condition and surgeons' preference. Until now, there is still debate which procedure is superior in terms of quality of life (QoL). In this study we compare QoL during the first six months of treatment in patients undergoing LAR and APR.

Materials and Methods: This study was performed in the context of the Prospective data CollectioN Initiative on Colorectal cancer (PICNIC) cohort. Within PICNIC patients fill out standardized QoL questionnaires at start of radiotherapy and every 3 months thereafter. In the present study, participants with rectal cancer who underwent curative surgery following radiotherapy between February 2013 and September 2014 were included. QoL was measured by means of EORTC QLQ-C30 and CR29, at baseline, 3 and 6 months. Responses were transformed to a longitudinal scale and reported as mean or median, depending on distribution. Mean differences in QoL scores were calculated and categorized as improved, stable and worsened. Differences in QoL were tested on significance with the Mann-Whitney U test and Chi-square test.

Results: One-hundred-fourteen patients were identified, 55 (48%) underwent APR and 59 (52%) LAR. Baseline characteristics between were similar for both groups, except for tumor location (90.9% vs. 28.8% located in lower third of the rectum for APR and LAR resp.) and T-stage (66.7% vs. 83.1% T3 tumors for APR and LAR resp.). At baseline, LAR patients reported a higher mean score for physical function (90 vs. 82, p = 0.008), role function (84 vs. 72, p = 0.008) and

global health (75 vs. 66, p = 0.013) compared to APR patients. After 3 months, both groups reported similar differences in QoL function scales. At 6 months, global health recovered in APR patients to baseline levels or above (only 22.6% reported to worsen compared to baseline), while LAR patients showed slower recovery (with 43.5% worsened status). At 6 months, APR patients had worsened body image compared to LAR patients (mean difference -19 (-26.7 to -11.3) vs. -11 (15.8 to -6.8), p = 0.01), but improved stool frequency (mean difference +18 (7.9 to 28.8) resp. -6 (-15.4 to 3.9) p = 0.003). Regarding symptoms, LAR patients worsened on embarrassment for defecation pattern, while APR patients worsened on urine incontinence and impotence.

Conclusions: The impact of surgery type on QoL during the first six months in rectal cancer patients pretreated with (chemo)radiation is similar for most domains. However, patients who underwent APR seem to recover more quickly in respective of their global QoL before treatment. Symptom patterns were quite different between patients undergoing LAR or APR. These results can be helpful in counseling patients in treatment choice, giving the large differences in patients' perspective, lifestyle, and expectations of treatment.

OC-0611

Interim analysis of postoperative chemoradiotherapy for locally advanced rectal cancer: a phase 3 trial

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Purpose/Objective: To present an interim analysis of the trial of concurrent capecitabine and radiotherapy with or without oxaliplatin as adjuvant treatment for locally advanced rectal cancer.

Materials and Methods: This was a multicentre, open-label, randomized, phase 3 study in patients with pathological stage II-III rectal cancer. Patients were randomized to either radiotherapy 45-50.4 Gy/25-28 fractions with concurrent capecitabine 1600 mg/m² on days 1-14, 22-35 (Cap-RT group) or 45-50.4 Gy/25-28 fractions with capecitabine 1300 mg/m² on days 1-14, 22-35 and oxaliplatin 60 mg/m² on weeks 1, 2, 4, 5 (Capox-RT group). Randomization was done with computer-generated block-randomization codes stratified by centre and pathological stage (II vs. III) without masking. The primary endpoint was 3-year disease-free survival rate (DFS); secondary endpoints included overall survival rate (OS), locoregional failure free survival rate (LRFFS), distant metastasis free survival rate (DMFS), compliance, and safety. Safety and compliance analyses included patients as treated, efficacy endpoints were analysed according to the intention-to-treat principle. This study is registered with ClinicalTrials.gov, number NCT00714077.

Results: Providing 80% power to detect an increase of 3y-DFS from 65% to 75% ($\alpha=0.05$, 2-tailed test), 570 patients were required. Between January 2008 and July 2014, 492 patients were recruited from 4 centers in China. Of these patients, 478 were evaluable (254 in the Cap-RT group and 224 in the Capox-RT group), with a median follow-up of 34.6 months for patients alive. The 3-year DFS rate was 71.6% in the Capox-RT group, as compared with 73.9% in the Cap-RT group (p = 0.647). No statistically significant difference was observed in OS, LRFFS, and DMFS between the two groups (3-year OS: 88.1% vs. 85.4%, p = 0.770; LRFFS: 91.9% vs. 96.1%, p = 0.079; DMFS: 76.1% vs. 74.3%, p = 0.934), but higher cumulative locoregional recurrence rate in the Cap-RT group (6.7% vs.